Keith J. Miller, Esq.
ROBINSON MILLER LLC
One Newark Center
Newark, NJ 07102
973-690-5400
kmiller@rwmlegal.com

Attorney for Gilead Sciences, Inc. and Gilead Pharmasset LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GILEAD SCIENCES, INC. and GILEAD PHARMASSET LLC, Plaintiffs, v. NATCO PHARMA LIMITED, NATCO PHARMA INC., and INC RESEARCH, LLC, Defendant(s).	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Gilead Sciences, Inc. and Gilead Pharmasset LLC (collectively, "Gilead" or "Plaintiffs"), by their undersigned attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendants Natco Pharma Limited ("Natco Ltd."), Natco Pharma Inc. ("Natco Inc."), and INC Research, LLC ("INC") (collectively, "Natco" or "Defendants"). This action arises out of the filing by Natco of Abbreviated New Drug Application ("ANDA") No. 211373 with the United States Food and Drug Administration ("FDA").

2. In ANDA No. 211373, Natco seeks approval to market a generic version of Gilead's groundbreaking Sovaldi® product (the "Natco ANDA Product"), prior to the expiration of U.S. Patent Nos. 8,618,076 (the "'076 patent"); 9,284,342 (the "'342 patent"); 7,429,572 (the "'572 patent"); 8,415,322 (the "'322 patent"); 9,206,217 (the "'217 patent"); and 9,340,568 (the "'568 patent") (collectively, the "patents-in-suit").

PARTIES

3. Plaintiff Gilead Sciences, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

4. Plaintiff Gilead Pharmasset LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 303-A College Road East, Princeton, New Jersey 08540.

5. Gilead Sciences, Inc. is a research-based pharmaceutical company that discovers, develops, and brings to market revolutionary pharmaceutical products in areas of unmet medical need, including treatments for hepatitis C virus ("HCV"), hepatitis B virus ("HBV"), human immunodeficiency virus ("HIV"), liver diseases, serious cardiovascular and respiratory diseases, and cancer. Gilead's portfolio of products includes treatments for chronic HCV infection using the drug sofosbuvir. Gilead sells sofosbuvir under the trade name Sovaldi® in this District and throughout the United States.

6. On information and belief, Defendant Natco Ltd. is a foreign limited liability company organized and existing under the laws of India, having its principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad, 500034, India.

7. On information and belief, Defendant Natco Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 297 Mine Bank Road, Wellsville, Pennsylvania 17365.

8. On information and belief, Natco Inc. is a wholly-owned subsidiary of Natco Ltd. and is controlled and/or dominated by Natco Ltd. Natco Inc. is in the business of, among other things, the retail sale of prescription drugs, proprietary drugs, and non-prescription medicines.

9. On information and belief, Defendant INC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 3201 Beechleaf Court, Suite 600, Raleigh, North Carolina 27604.

10. On information and belief, INC is the United States agent for Natco Ltd., and is in the business of, among other things, performing contract research for pharmaceutical companies.

11. On information and belief, INC is a wholly-owned subsidiary of Syneos Health, a company that is in the business of, among other things, clinical development and consulting for pharmaceutical companies. On information and belief, Syneos Health maintains a regular and established place of business at 202 Carnegie Drive, Princeton, New Jersey 08540 and 301 College Road East, Princeton, New Jersey 08540.

12. On information and belief, Defendants, themselves and through their subsidiaries, affiliates, and agents, manufacture, distribute, and/or import generic drugs for sale and use throughout the United States, including in this District.

13. On information and belief, Defendants are agents of each other and/or work in concert with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products, including the Natco ANDA Product, throughout the United States, including in this District.

14. On information and belief, Defendants prepared and filed ANDA No. 211373 and will be involved in the manufacture, importation, marketing and sale of the Natco ANDA Product in the United States, including in this District, if ANDA No. 211373 is approved.

JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

16. On information and belief, Natco Ltd., acting in concert with Natco Inc. and INC, develops, formulates, manufactures, imports, offers for sale, sells, commercializes, markets, and/or distributes generic pharmaceutical products in or into the United States, including in or into the State of New Jersey.

17. On information and belief, Natco Ltd., acting in concert with Natco Inc. and INC, prepared and filed ANDA No. 211373, seeking approval from FDA to sell the Natco ANDA Product throughout the United States, including within the State of New Jersey.

18. By submitting ANDA No. 211373 to FDA, Natco Ltd., acting in concert with Natco Inc. and INC, has made clear that it intends to use its distribution channels to market the Natco ANDA Product in the State of New Jersey. If ANDA No. 211373 is approved, the Natco ANDA Product would, among other things, be marketed and distributed in the State of New Jersey, and/or prescribed by physicians practicing and dispensed by pharmacies located within the State of New Jersey, all of which would have a substantial effect on the State of New Jersey.

19. On information and belief, Natco Inc., acting in concert with Natco Ltd. and INC, participated in the preparation and/or filing of ANDA No. 211373, seeking approval from FDA to sell the Natco ANDA Product throughout the United States, including within the State of New Jersey.

20. On information and belief, INC, acting in concert with Natco Ltd. and Natco Inc., participated in the preparation and/or filing of ANDA No. 211373, seeking approval from FDA to sell the Natco ANDA Product throughout the United States, including within the State of New Jersey.

21. Natco Ltd., Natco Inc., and INC therefore committed an act of infringement in the State of New Jersey, by participating in the preparation, filing, and submission of ANDA No. 211373 pursuant to § 505(j) of the Federal Food Drug and Cosmetic Act to FDA, accompanied by a Paragraph IV certification.

22. This Court has personal jurisdiction over Natco Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Gilead's claims arise under federal law; (b) Natco Ltd. is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Natco Ltd. has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Natco Ltd. satisfies due process.

23. This Court has personal jurisdiction over Natco Inc. because, on information and belief, Natco Inc., either directly or through its agents and/or affiliates: (1) regularly and continuously transacts and/or solicits business in this District, including by, among other things, preparing, selling and distributing pharmaceutical products in the State of New Jersey; (2) maintains substantial, systemic, and continuous contacts with the State of New Jersey; (3) continuously and systematically places its products into the stream of commerce for distribution and consumption in the State of New Jersey and throughout the United States; (4) derives substantial revenue and income from sales of pharmaceutical products throughout the United States, including in the State of New Jersey; and (5) intends to manufacture for distribution,

market, sell, offer to sell, and/or distribute the Natco ANDA Product, if approved, to residents of the State of New Jersey.

24. This Court has personal jurisdiction over INC because, on information and belief, INC, either directly or through its agents and/or affiliates: (1) regularly and continuously transacts and/or solicits business in this District, including by, among other things, performing contract research services for pharmaceutical companies in the State of New Jersey; (2) maintains substantial, systemic, and continuous contacts with the State of New Jersey; (3) derives substantial revenue and income from transacting business throughout the United States, including in the State of New Jersey, by, among other things, performing contract research services for pharmaceutical companies; and (4) intends to market, sell, offer to sell, and/or distribute the Natco ANDA Product, if approved, to residents of the State of New Jersey.

25. This Court also has personal jurisdiction over INC because, on information and belief, INC is registered to do business in the State of New Jersey and has also designated Corporation Service Company as its agent for service of process therein. Corporation Service Company is located at Princeton South Corporate Center, Suite 160, 100 Charles Ewing Boulevard, Ewing, New Jersey 08628.

26. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) and 1400(b) because Natco Ltd. is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

27. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) because Natco Inc. committed an act of infringement in this District and has a regular and established place of business in this District. On information and belief, Natco Inc., acting as an agent of and/or working in concert with Natco Ltd., participated in the preparation, filing, and submission of

ANDA No. 211373, seeking FDA approval to sell the Natco ANDA Product, throughout the United States, including in this District. Further, on information and belief, if ANDA No. 211373 is approved, Natco Inc., acting as an agent of and/or working in concert with Natco Ltd., intends to manufacture, offer for sale, sell, and/or distribute the Natco ANDA Product to residents of the State of New Jersey. Natco Inc. has thus committed an act of infringement in this District. On information and belief, Natco Ltd. has a regular and established place of business at 58 Kelly Way, Monmouth Junction, New Jersey 08852. On information and belief, Natco Inc. is the alter-ego of Natco Ltd., and thus also has a regular and established place of business at the same address.

28. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) because INC committed an act of infringement in this District and has a regular and established place of business in this District. On information and belief, INC, acting as an agent of and/or working in concert with Natco Ltd., participated in the preparation, filing, and submission of ANDA No. 211373, seeking FDA approval to sell the Natco ANDA Product, throughout the United States, including in this District. Further, on information and belief, if ANDA No. 211373 is approved, INC, acting as an agent of and/or working in concert with Natco Ltd., intends to manufacture, offer for sale, sell, and/or distribute the Natco ANDA Product to residents of the State of New Jersey. INC has thus committed an act of infringement in this District. On information and belief, Syneos Health is the corporate parent of INC and maintains a regular and established place of business at 202 Carnegie Drive Princeton, New Jersey 08540 and 301 College Road East Princeton, New Jersey 08540. On information and belief, INC is the alter-ego of Syneos Health, and thus also has a regular and established place of business at the same addresses.

PATENTS-IN-SUIT

29. On December 21, 2013, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,618,076 (the "'076 patent"), titled, "Nucleoside Phosphoramidates." A

true and correct copy of the '076 patent is attached hereto as Exhibit A. The claims of the '076 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '076 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

30. On March 15, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,284,342 (the "'342 patent"), titled, "Nucleoside Phosphoramidates." A true and correct copy of the '342 patent is attached hereto as Exhibit B. The claims of the '342 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '342 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

31. On September 30, 2008, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 7,429,572 (the "'572 patent"), titled "Modified Fluorinated Nucleoside Analogues." A true and correct copy of the '572 patent is attached hereto as Exhibit C. The claims of the '572 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '572 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

32. On April 9, 2013, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,415,322 (the "'322 patent"), titled "Modified Fluorinated Nucleoside Analogues." A true and correct copy of the '322 patent is attached hereto as Exhibit D. The claims of the '322 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '322 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

33. On December 8, 2015, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,206,217 (the "'217 patent"), titled, "Nucleoside Phosphoramidates." A true and correct copy of the '217 patent is attached hereto as Exhibit E. The claims of the '217 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '217 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

34. On May 17, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,340,568 (the "'568 patent"), titled, "Solid Forms of an Antiviral Compound." A true and correct copy of the '568 patent is attached hereto as Exhibit F. The claims of the '568 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '568 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

ACTS GIVING RISE TO THIS ACTION

35. Gilead Sciences, Inc. holds New Drug Application ("NDA") No. 204671 for 400 mg sofosbuvir tablets for the treatment of adult patients with genotype 1, 2, 3 or 4 chronic hepatitis C virus infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen, and for the treatment of pediatric patients 12 years of age and older or weighing at least 35 kg with genotype 2 or 3 chronic hepatitis C virus infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.

36. The 400 mg sofosbuvir tablets approved under the NDA are marketed in the United States under the trade name Sovaldi®. FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") identifies the following patents as covering Sovaldi®: U.S. Patent Nos. 7,964,580; 8,334,270; 8,580,765; 9,085,573; 8,633,309; 9,284,342; 8,618,076; 9,549,941; and 8,889,159.

37. On or about February 8, 2018, Gilead received a letter, dated February 7, 2018, from Natco (the "Notice Letter"). The Notice Letter states that Natco had submitted, and FDA had received, an ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Natco's ANDA number is 211373.

38. The Notice Letter further states that Natco had submitted ANDA No. 211373 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of the Natco ANDA Product before the expiration of U.S. Patent Nos. 8,618,076 and 9,284,342.

39. In the Notice Letter, Natco states that its ANDA includes a certification pursuant to 21 U.S.C. § 505(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) with respect to the '076 and '342 patents. The Notice Letter further alleges that these patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, and sale of the Natco ANDA Product in the United States. In the Notice Letter, Natco states that the Natco ANDA Product does not infringe Claims 8-12, 16-20, 24-28, and 32-36 of the '076 patent, and that claims 1-7, 13-15, 21-23 and 29-31 of the '076 patent and all claims of the '342 patent are invalid.

40. By filing ANDA No. 211373, Natco has necessarily represented to FDA that the Natco ANDA Product has the same active ingredient as Sovaldi®, has the same dosage form and strength as Sovaldi®, and is bioequivalent to Sovaldi®.

41. On information and belief, Natco is seeking approval to market the Natco ANDA Product for the same approved indication as Sovaldi®.

42. The Notice Letter included an Offer of Confidential Access ("OCA") to ANDA No. 211373 under 21 U.S.C. § 355(j)(5)(C)(i)(III) on terms and conditions set forth in the Notice Letter. Natco requested that Gilead accept the OCA before receiving access to Natco's ANDA. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." The OCA contained unreasonable restrictions, above and beyond those that would apply under a protective order, on who could view the ANDA. For example, the OCA unreasonably limited the fields of practice and other activities of outside counsel and any other person who accepted access to the ANDA. The OCA also did

not permit Gilead to share the ANDA with in-house counsel or experts. The OCA further did not allow Gilead access to Natco's entire ANDA, its correspondence with FDA regarding the ANDA, or its Drug Master File.

43. Since receiving the Notice Letter, Gilead and Natco have been negotiating in good faith to reach a mutually-acceptable agreement under which Natco's ANDA would be provided to Gilead. To date, the parties have been unable to reach agreement. For example, Natco's most recent proposal continues to unreasonably limit the fields of practice and other activities of any person, including outside counsel, who accepts access to the ANDA. Natco also continues to refuse to give Gilead access to Natco's entire ANDA, its correspondence with FDA regarding the ANDA, or its Drug Master File. Natco also would not agree to permit Gilead to share the ANDA with in-house scientists or a reasonable number of Gilead in-house counsel. As a result, Gilead has been unable to access Natco's ANDA.

44. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter in order to receive certain benefits under the Act, including a stay of approval of the generic drug for up to 30 months during the pendency of litigation, as appropriate. 21 U.S.C. § 355 (c)(3)(c).

45. Gilead is not aware of any other means of obtaining information regarding the Natco ANDA Product within the 45-day statutory period. In the absence of such information, Gilead resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm its belief and to present to the Court evidence that Natco infringes certain claims of the patents-in-suit.

46. This action is being commenced before the expiration of 45 days from the date Gilead received the Notice Letter, which triggers a stay of FDA approval of Natco's ANDA No. 211373, pursuant to 21 U.S.C. § 355(J)(5)(B)(iii).

COUNT I

(INFRINGEMENT OF THE '076 PATENT UNDER 35 U.S.C. § 271(e)(2))

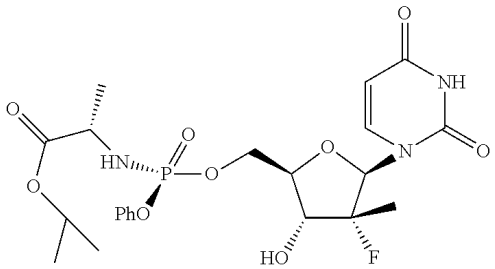
47. Gilead realleges paragraphs 1-46 as if fully set forth herein.

48. Pursuant to 35 U.S.C. § 271(e)(2)(A), Natco has committed an act of infringement with respect to the '076 patent by submitting ANDA No. 211373 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product in the United States prior to the expiration of the '076 patent.

49. Natco's commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product prior to the expiration of the '076 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '076 patent, including but not limited to claim 1.[1]

50. For example, on information and belief, the Natco ANDA Product contains a crystalline compound represented by the following formula:

(S_p-4)



having XRPD 2θ-reflections (°) at about: 6.1, 8.2, 10.4, 12.7, 17.2, 17.7, 18.0, 18.8, 19.4, 19.8, 20.1, 20.8, 21.8, and 23.3, and thus falls within the scope of at least claim 1 of the '076 patent.

[1] Gilead will identify all asserted claims of the '076 patent in accordance with this Court's Local Rules and/or scheduling order.

51. If Natco's marketing and sale of the Natco ANDA Product prior to expiration of the '076 patent and all other relevant exclusivities is not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '076 PATENT UNDER 35 U.S.C. §§ 271(a)-(c), (g))

52. Gilead realleges paragraphs 1-51 as if fully set forth herein.

53. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

54. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

55. Natco has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Natco intends to manufacture, use, offer for sale, sell, and/or import the Natco ANDA Product within the United States.

56. While ANDA No. 211373 has not been approved by FDA, Natco has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import the Natco ANDA Product.

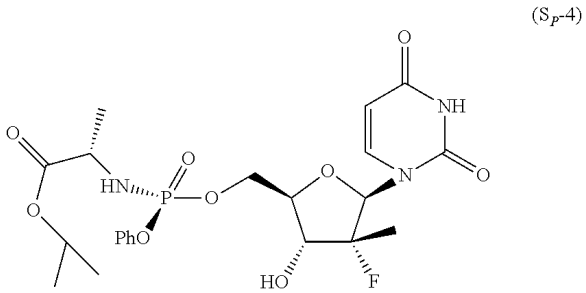
57. Natco's recent actions indicate that it does not intend to change its course of conduct.

58. On information and belief, upon FDA approval of Natco's ANDA No. 211373, Natco will infringe one or more claims of the '076 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[2] by making, using, offering to sell, and selling

[2] Gilead will identify all asserted claims of the '076 patent in accordance with this Court's Local Rules and/or scheduling order.

the Natco ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing and contributing to infringement of the ’076 patent by others, under 35 U.S.C. § 271(a), (b), (c), and/or (g), unless enjoined by the Court.

59. For example, on information and belief, the Natco ANDA Product contains a crystalline compound represented by the following formula:



having XRPD 2θ-reflections (°) at about: 6.1, 8.2, 10.4, 12.7, 17.2, 17.7, 18.0, 18.8, 19.4, 19.8, 20.1, 20.8, 21.8, and 23.3, and thus falls within the scope of at least claim 1 of the ’076 patent.

60. Natco has actual knowledge of the ’076 patent.

61. On information and belief, Natco became aware of the ’076 patent no later than the date on which that patent was listed in the Orange Book.

62. On information and belief, Natco has acted with full knowledge of the ’076 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the ’076 patent. Further, on information and belief, Natco knows, or is willfully blind to the fact that, the commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product will constitute infringement of the ’076 patent. On information and belief, this knowledge is reflected through, among other things, Natco’s Notice Letter, which does not contest infringement of claims 1-7, 13-15, 21-23, and 29-31 of the ’076 patent.

63. On information and belief, the Natco ANDA Product, if approved by FDA, will be commercially manufactured, imported, offered for sale, and/or sold by Natco in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '076 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(a). On information and belief, the administration of the Natco ANDA Product will occur with Natco's specific intent and encouragement, and will be conduct that Natco knows or should know will occur. On information and belief, Natco will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '076 patent.

64. On information and belief, Natco's commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product, once ANDA No. 211373 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '076 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(b).

65. On information and belief, Natco's commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product, once ANDA No. 211373 is approved by FDA, would contribute to infringement of at least one of the claims of the '076 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(c). On information and belief, Natco knows or should know that the Natco ANDA Product

will be especially made or adapted for use in infringing the ’076 patent, and that the Natco ANDA Product is not suitable for substantial non-infringing use.

66. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product by Natco prior to the expiration of the ’076 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the ’076 patent.

67. If Natco’s marketing and sale of the Natco ANDA Product prior to expiration of the ’076 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III

(INFRINGEMENT OF THE ’342 PATENT UNDER 35 U.S.C. § 271(e)(2))

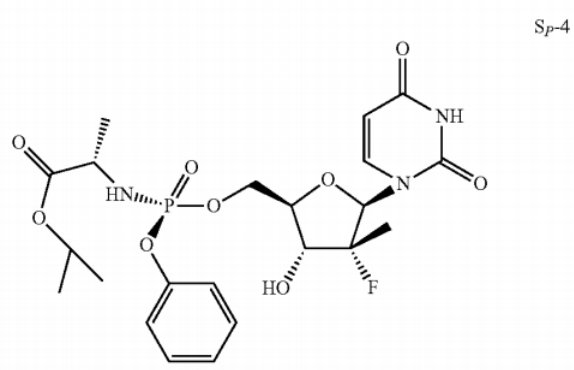
68. Gilead realleges paragraphs 1-67 as if fully set forth herein.

69. Pursuant to 35 U.S.C. § 271(e)(2)(A), Natco has committed an act of infringement with respect to the ’342 patent by submitting ANDA No. 211373 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product in the United States prior to the expiration of the ’342 patent.

70. Natco’s commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product prior to the expiration of the ’342 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the ’342 patent, including but not limited to claim 1.[3]

71. For example, on information and belief, the Natco ANDA Product contains a crystalline compound represented by the following formula:

[3] Gilead will identify all asserted claims of the ’342 patent in accordance with this Court’s Local Rules and/or scheduling order.



having XRPD 2θ-reflections (°) at about: 6.1 and 12.7, and thus falls within the scope of at least claim 1 of the ’342 patent.

72. If Natco’s marketing and sale of the Natco ANDA Product prior to expiration of the ’342 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’342 PATENT UNDER 35 U.S.C. §§ 271(a)-(c))

73. Gilead realleges paragraphs 1-72 as if fully set forth herein.

74. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

75. There is an actual case or controversy such that the Court may entertain Gilead’s request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

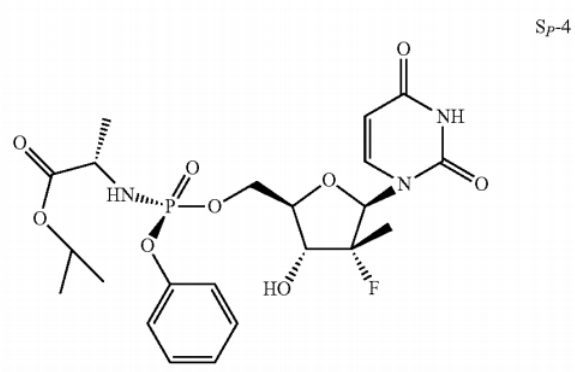
76. Natco has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Natco intends to manufacture, use, offer for sale, sell, and/or import the Natco ANDA Product within the United States.

77. While ANDA No. 211373 has not been approved by FDA, Natco has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the Natco ANDA Product.

78. Natco's recent actions indicate that it does not intend to change its course of conduct.

79. On information and belief, upon FDA approval of Natco's ANDA No. 211373, Natco will infringe one or more claims of the '342 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[4] by making, using, offering to sell, and selling the Natco ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing and contributing to infringement of the '342 patent by others, under 35 U.S.C. § 271(a), (b) and/or (c), unless enjoined by the Court.

80. For example, on information and belief, the Natco ANDA Product contains a crystalline compound represented by the following formula:



having XRPD 2θ-reflections (°) at about: 6.1 and 12.7, and thus falls within the scope of at least claim 1 of the '342 patent.

81. Natco has actual knowledge of the '342 patent.

82. On information and belief, Natco became aware of the '342 patent no later than the date on which that patent was listed in the Orange Book.

[4] Gilead will identify all asserted claims of the '342 patent in accordance with this Court's Local Rules and/or scheduling order.

83. On information and belief, Natco has acted with full knowledge of the '342 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '342 patent. Further, on information and belief, Natco knows, or is willfully blind to the fact that, the commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product will constitute infringement of the '342 patent. On information and belief, this knowledge is reflected through, among other things, Natco's Notice Letter, which does not contest infringement of any claim of the '342 patent.

84. On information and belief, the Natco ANDA Product, if approved by FDA, will be commercially manufactured, imported, offered for sale, and/or sold by Natco in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '342 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(a). On information and belief, the administration of the Natco ANDA Product will occur with Natco's specific intent and encouragement, and will be conduct that Natco knows or should know will occur. On information and belief, Natco will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '342 patent.

85. On information and belief, Natco's commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product, once ANDA No. 211373 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the

claims of the ’342 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(b).

86. On information and belief, Natco’s commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product, once ANDA No. 211373 is approved by FDA, would contribute to infringement of at least one of the claims of the ’342 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(c). On information and belief, Natco knows that the Natco ANDA Product is especially made or adapted for use in infringing the ’342 patent, and that the Natco ANDA Product is not suitable for substantial non-infringing use.

87. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Natco ANDA Product by Natco prior to the expiration of the ’342 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the ’342 patent.

88. If Natco’s marketing and sale of the Natco ANDA Product prior to expiration of the ’342 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT V

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’572 PATENT)

89. Gilead realleges paragraphs 1-88 as if fully set forth herein.

90. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

91. There is an actual case or controversy such that the Court may entertain Gilead’s request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

92. Natco has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Natco intends to manufacture, use, offer for sale, sell, and/or import the Natco ANDA Product within the United States.

93. While ANDA No. 211373 has not been approved by FDA, Natco has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import the Natco ANDA Product.

94. Natco's recent actions indicate that it does not intend to change its course of conduct.

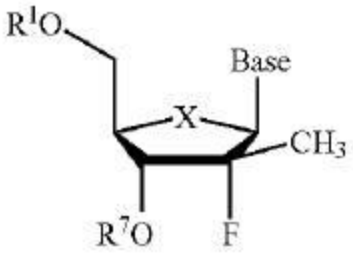
95. Natco became aware of the '572 patent no later than the date of filing of this Complaint. As a result, Natco has knowledge of the '572 patent and will have knowledge of the '572 patent when it manufactures, uses, offers for sale, sells and/or imports the Natco ANDA Product within the United States.

96. The claims of the '572 patent relate to, *inter alia*, certain metabolites of sofosbuvir and certain intermediates that can be used in making sofosbuvir.

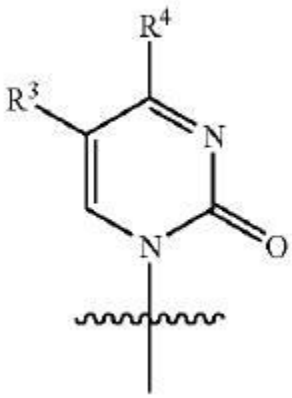
97. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product by Natco prior to the expiration of the '572 patent will directly and/or indirectly infringe, contribute to the infringement of and/or induce infringement of, either literally or under the doctrine of equivalents, at least one of the claims of the '572 patent, under 35 U.S.C. § 271(a), (b) and/or (c), including but not limited to claim 1.[5]

98. For example, on information and belief, the Natco ANDA Product contains, will metabolize into, and/or will be manufactured using a (2'R)-2'-deoxy-2'-fluoro-2'-C-methyl nucleoside (β-D or β-L) or its pharmaceutically acceptable salt of the structure:

[5] Gilead will identify all asserted claims of the '572 patent in accordance with this Court's Local Rules and/or scheduling order.



wherein Base is a pyrimidine base represented by the following formula:



wherein X is O; R^1 is H, a monophosphate, a diphosphate, or a triphosphate, R^7 is H; R^3 is H, and R^4 is OH, and thus falls within the scope of at least claim 1 of the '572 patent.

99. On information and belief, the Natco ANDA Product, if approved by FDA, will be commercially manufactured, imported, offered for sale, and/or sold by Natco in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(a). On information and belief, the administration of the Natco ANDA Product will occur with Natco's specific intent and encouragement, and will be conduct that Natco knows or should know will occur. On information and belief, Natco will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with

knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '572 patent.

100. On information and belief, Natco's commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product, once ANDA No. 211373 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(b).

101. On information and belief, Natco's commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product, once ANDA No. 211373 is approved by FDA, would contribute to infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(c). On information and belief, Natco knows or should know that the Natco ANDA Product will be especially made or adapted for use in infringing the '572 patent, and that the Natco ANDA Product is not suitable for substantial non-infringing use.

102. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product by Natco prior to expiration of the '572 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '572 patent.

103. If Natco's manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product prior to expiration of the '572 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VI

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '322 PATENT)

104. Gilead realleges paragraphs 1-103 as if fully set forth herein.

105. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

106. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

107. Natco has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Natco intends to manufacture, use, offer for sale, sell, and/or import the Natco ANDA Product within the United States.

108. While ANDA No. 211373 has not been approved by FDA, Natco has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the Natco ANDA Product.

109. Natco's recent actions indicate that it does not intend to change its course of conduct.

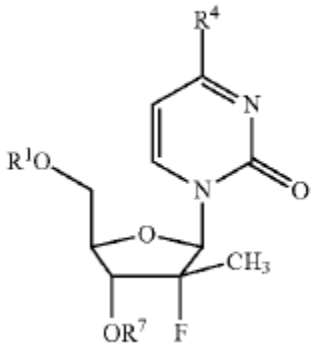
110. Natco became aware of the '322 patent no later than the date of filing of this Complaint. As a result, Natco has knowledge of the '322 patent and will have knowledge of the '322 patent when it manufactures, uses, offers for sale, sells, and/or imports the Natco ANDA Product within the United States.

111. The claims of the '322 patent relate to methods of inhibiting proliferation of hepatitis C virus or the treatment of a hepatitis C virus infection with metabolites of sofosbuvir.

112. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product by Natco prior to the expiration of the '322 patent will directly and/or indirectly infringe, contribute to the infringement of and/or induce

infringement of, either literally or under the doctrine of equivalents, at least one of the claims of the '322 patent, under 35 U.S.C. § 271(a), (b) and/or (c), including but not limited to claim 9.[6]

113. On information and belief, for example, the use of the Natco ANDA Product, in accordance with its label, will inhibit the proliferation of hepatitis C virus in a human subject infected with the virus by a method comprising providing to the subject an antivirally effective amount of a compound of the following structure, which is formed during the metabolism of the Natco ANDA Product:



or its pharmaceutically acceptable salt wherein R^1 is triphosphate; R^7 is H; and R^4 is OH, and thus falls within the scope of at least claim 9 of the '322 patent.

114. On information and belief, the Natco ANDA Product, if approved by FDA, will be commercially manufactured, imported, offered for sale, and/or sold by Natco in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '322 patent, including but not limited to claim 9, under 35 U.S.C. § 271(a), either literally

[6] Gilead will identify all asserted claims of the '322 patent in accordance with this Court's Local Rules and/or scheduling order.

or under the doctrine of equivalents. On information and belief, the administration of the Natco ANDA Product will occur with Natco's specific intent and encouragement, and will be conduct that Natco knows or should know will occur. On information and belief, Natco will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '322 patent.

115. On information and belief, Natco's commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product, once ANDA No. 211373 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '322 patent, either literally or under the doctrine of equivalents, including but not limited to claim 9, under 35 U.S.C. § 271(b).

116. On information and belief, Natco's commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product, once ANDA No. 211373 is approved by FDA, would contribute to infringement of at least one of the claims of the '322 patent, either literally or under the doctrine of equivalents, including but not limited to claim 9, under 35 U.S.C. § 271(c). On information and belief, Natco knows or should know that the Natco ANDA Product will be especially made or adapted for use in an infringement of the '322 patent, and the Natco ANDA Product is not suitable for substantial non-infringing use.

117. Gilead is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of the Natco ANDA Product by Natco prior to expiration

of the ’322 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the ’322 patent.

118. If Natco’s marketing and sale of the Natco ANDA Product prior to expiration of the ’322 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VII

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’217 PATENT)

119. Gilead realleges paragraphs 1-118 as if fully set forth herein.

120. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

121. There is an actual case or controversy such that the Court may entertain Gilead’s request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

122. Natco has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Natco intends to manufacture, use, offer for sale, sell, and/or import the Natco ANDA Product within the United States.

123. While ANDA No. 211373 has not been approved by FDA, Natco has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the Natco ANDA Product.

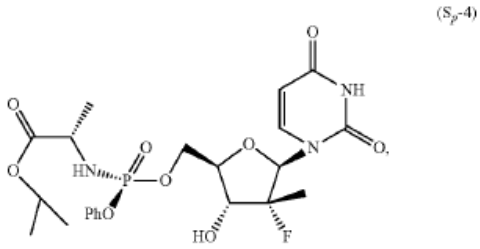
124. Natco’s recent actions indicate that it does not intend to change its course of conduct.

125. Natco became aware of the ’217 patent no later than the date of filing of this Complaint. As a result, Natco has knowledge of the ’217 patent and will have knowledge of the ’217 patent when it manufactures, uses, offers for sale, sells, and/or imports the Natco ANDA Product within the United States.

126. The claims of the ’217 patent relate to crystalline forms of sofosbuvir.

127. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product by Natco prior to the expiration of the ’217 patent will directly and/or indirectly infringe, contribute to the infringement of and/or induce infringement of, either literally or under the doctrine of equivalents, at least one of the claims of the ’217 patent, under 35 U.S.C. § 271(a), (b) and/or (c), including but not limited to claims 1 and 2.[7]

128. For example, on information and belief, in the commercial manufacture, use, offer to sell, sale, and/or importation of the Natco ANDA Product, Natco will manufacture a compound represented by the formula (Sp-4):

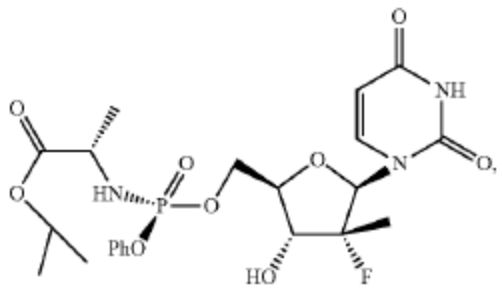


wherein the compound is monoclinic crystalline (Sp-4) having unit cell parameters: (i) a~12.88 Å, b~6.17 Å, c~17.73 Å, and β~92.05°; (ii) a~20.09 Å, b~6.10 Å, c~23.01 Å, and β~112.29°; (iii) a~12.83 Å, b~6.15 Å, c~17.63 Å, and β~91.75°; or (iv) a~12.93 Å, b~6.18 Å, c~18.01 Å, and β~96.40°, and thus falls within the scope of at least claim 1 of the ’217 patent.

129. Similarly, on information and belief, in the commercial manufacture, use, offer to sell, sale, and/or importation of the Natco ANDA Product, Natco will manufacture a compound represented by the formula (Sp-4):

[7] Gilead will identify all asserted claims of the ’217 patent in accordance with this Court’s Local Rules and/or scheduling order.

(S_p-4)



wherein the compound is monoclinic crystalline having XRPD 2θ-reflections (°) at about: (i) 5.2, 7.5, 9.6, 16.7, 18.3, and 22.2; (ii) 5.0, 7.3, 9.4, and 18.1; (iii) 4.9, 6.9, 9.8, 19.8, 20.6, 24.7, and 26.1; (iv) 6.9, 9.8, 19.7, 20.6, and 24.6; (v) 5.0, 6.8, 19.9, 20.6, 20.9, and 24.9; or (vi) 5.2, 6.6, 7.1, 15.7, 19.1, and 25.0, and thus falls within the scope of at least claim 2 of the ’217 patent.

130. On information and belief, the Natco ANDA Product, if approved by FDA, will be commercially manufactured, imported, offered for sale, and/or sold by Natco in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the ’217 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 2, under 35 U.S.C. § 271(a). On information and belief, the administration of the Natco ANDA Product will occur with Natco’s specific intent and encouragement, and will be conduct that Natco knows or should know will occur. On information and belief, Natco will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead’s rights under the ’217 patent.

131. On information and belief, Natco's commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product, once ANDA No. 211373 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '217 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 2, under 35 U.S.C. § 271(b).

132. On information and belief, Natco's commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product, once ANDA No. 211373 is approved by FDA, would contribute to infringement of at least one of the claims of the '217 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 2, under 35 U.S.C. § 271(c). On information and belief, Natco knows that the Natco ANDA Product is especially made or adapted for use in infringing the '217 patent, and that the Natco ANDA Product is not suitable for substantial non-infringing use.

133. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Natco ANDA Product by Natco prior to the expiration of the '217 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '217 patent.

134. If Natco's marketing and sale of the Natco ANDA Product prior to expiration of the '217 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VIII

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '568 PATENT)

135. Gilead realleges paragraphs 1-134 as if fully set forth herein.

136. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

137. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

138. Natco has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Natco intends to manufacture, use, offer for sale, sell, and/or import the Natco ANDA Product within the United States.

139. While ANDA No. 211373 has not been approved by FDA, Natco has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the Natco ANDA Product.

140. Natco's recent actions indicate that it does not intend to change its course of conduct.

141. Natco became aware of the '568 patent no later than the date of filing of this Complaint. As a result, Natco has knowledge of the '568 patent and will have knowledge of the '568 patent when it manufactures, uses, offers for sale, sells, and/or imports the Natco ANDA Product within the United States.

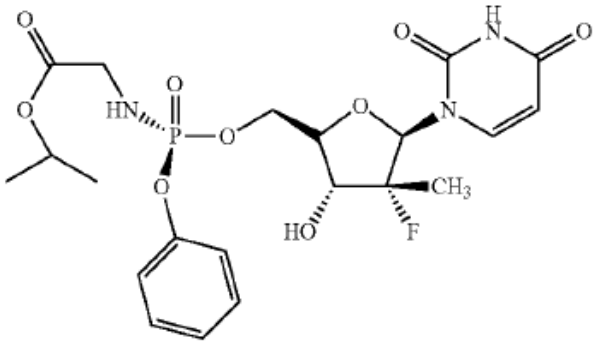
142. The claims of the '568 patent relate to crystalline forms of sofosbuvir.

143. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product by Natco prior to the expiration of the '568 patent will directly and/or indirectly infringe, contribute to the infringement of and/or induce infringement of, either literally or under the doctrine of equivalents, at least one of the claims of

the ’568 patent, under 35 U.S.C. § 271(a), (b) and/or (c), including but not limited to claims 1, 3, 5 and 7.[8]

144. For example, on information and belief, in the commercial manufacture, use, offer to sell, sale, and/or importation of the Natco ANDA Product, Natco will manufacture a crystalline compound I

(Compound I)

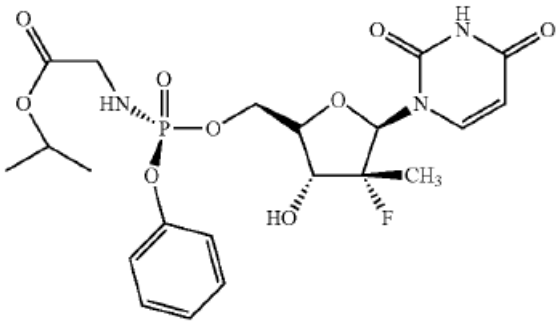


characterized by an XRPD spectrum comprising peaks at 12.6 and 13.5 °2θ±0.2° 2θ, and thus falls within the scope of at least claim 1 of the ’568 patent.

145. Similarly, on information and belief, in the commercial manufacture, use, offer to sell, sale, and/or importation of the Natco ANDA Product, Natco will manufacture a crystalline compound I

[8] Gilead will identify all asserted claims of the ’568 patent in accordance with this Court’s Local Rules and/or scheduling order.

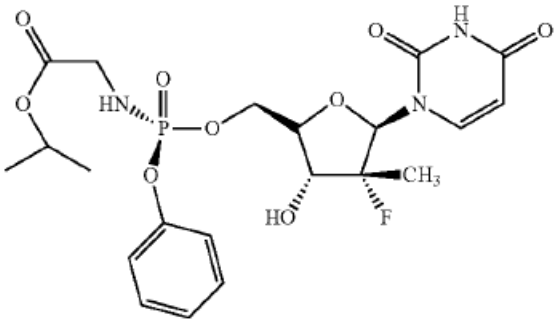
(Compound I)



characterized by a ^{13}C SSNMR spectrum comprising peaks at 18.6, 164.5, and 171.8 ppm±0.2 ppm, and thus falls within the scope of at least claim 3 of the '568 patent.

146. On information and belief, in the commercial manufacture, use, offer to sell, sale, and/or importation of the Natco ANDA Product, Natco will also manufacture a crystalline compound I

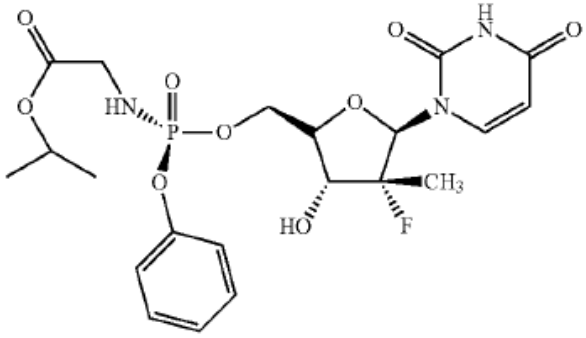
(Compound I)



characterized by an XRPD spectrum comprising peaks at 8.6, 9.2 and 17.1 °2θ±0.2° 2θ, and thus falls within the scope of at least claim 5 of the '568 patent.

147. On information and belief, in the commercial manufacture, use, offer to sell, sale, and/or importation of the Natco ANDA Product, Natco will also manufacture a crystalline compound I

(Compound I)



characterized by a ^{13}C SSNMR spectrum comprising peaks at 23.5, 70.1, and 152.4 ppm±0.2 ppm, and thus falls within the scope of at least claim 7 of the '568 patent.

148. On information and belief, the Natco ANDA Product, if approved by FDA, will be commercially manufactured, imported, offered for sale, and/or sold by Natco in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '568 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 3, 5, and 7, under 35 U.S.C. § 271(a). On information and belief, the administration of the Natco ANDA Product will occur with Natco's specific intent and encouragement, and will be conduct that Natco knows or should know will occur. On information and belief, Natco will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '568 patent.

149. On information and belief, Natco's commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product, once ANDA No. 211373 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the

claims of the ’568 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 3, 5, and 7, under 35 U.S.C. § 271(b).

150. On information and belief, Natco’s commercial manufacture, use, offer for sale, sale, and/or importation of the Natco ANDA Product, once ANDA No. 211373 is approved by FDA, would contribute to infringement of at least one of the claims of the ’568 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 3, 5, and 7, under 35 U.S.C. § 271(c). On information and belief, Natco knows that the Natco ANDA Product is especially made or adapted for use in infringing the ’568 patent, and that the Natco ANDA Product is not suitable for substantial non-infringing use.

151. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Natco ANDA Product by Natco prior to the expiration of the ’568 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the ’568 patent.

152. If Natco’s marketing and sale of the Natco ANDA Product prior to expiration of the ’568 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

EXCEPTIONAL CASE

153. Natco was aware of at least the ’076 and ’342 patents prior to filing an ANDA for a generic version of sofosbuvir and sending the Notice Letter to Gilead.

154. The actions of Natco render this an exceptional case under 35 U.S.C. § 285.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Gilead hereby demands a trial by jury of all issues that are or may become so triable.

PRAYER FOR RELIEF

WHEREFORE, Gilead prays that this Court grant the following relief:

a. A judgment that Natco has infringed the claims of U.S. Patent Nos. 8,618,076 and 9,284,342 by submitting ANDA No. 211373, and that Natco's making, using, offering to sell, or selling in the United States, and/or importing into the United States the Natco ANDA Product will infringe the claims of the '076 and '342 patents, either literally or under the doctrine of equivalents.

b. An order pursuant to 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271 declaring that Natco's manufacture, use, offer to sell, sale, or importation of the Natco ANDA Product in or into the United States prior to the expiration of U.S. Patent Nos. 8,618,076; 9,284,342; 7,429,572; 8,415,322; 9,206,217 and 9,340,568 will infringe and/or actively induce or contribute to the infringement of one or more claims of the '076, '342, '572, '322, '217, and '568 patents, and providing any further necessary or proper relief based on the Court's declaratory judgment or decree.

c. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 211373 shall be a date which is not earlier than the latest expiration date of the '076 and '342 patents, including any extensions and/or additional periods of exclusivity to which Gilead is or will be entitled.

d. An order under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Natco, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, and/or selling in the United States, and/or importing into the United States the Natco ANDA Product until after the latest expiration date of the patents-in-suit, including any extensions and/or additional periods of exclusivity to which Gilead is or will be entitled.

e. Damages or other monetary relief under 35 U.S.C. §§ 271(a), (b), (c) and (e)(4)(c), and/or 35 U.S.C. § 284, including costs, fees, pre- and post-judgment interest, to Gilead if Natco engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the Natco ANDA Product prior to the latest expiration date of the patents-in-suit, including any extensions and/or additional periods of exclusivity to which Gilead is or will be entitled.

f. An order that this case is exceptional under 35 U.S.C. § 285, and that Gilead be awarded reasonable attorneys' fees and costs; and

g. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: March 14, 2018

ROBINSON MILLER LLC

BY: *Keith J. Miller*
Keith J. Miller, Esq.
One Newark Center, 19th Floor
Newark, NJ 07102
(973) 690-5400
kmiller@rwmlegal.com

OF COUNSEL:
David B. Bassett
WILMER CUTLER PICKERING HALE & DORR LLP
7 World Trade Center
250 Greenwich Street
New York, New York 10007
(212) 230-8800
David.Bassett@wilmerhale.com

Vinita Ferrera
Emily Whelan
Shirley X. Li Cantin
WILMER CUTLER PICKERING HALE & DORR LLP
60 State Street

OF COUNSEL:

Gregory Booker
Robert M. Oakes
FISH & RICHARDSON P.C.
222 Delaware Avenue, 17th Floor
P.O. Box 1114
Wilmington, DE 19899-1114
Phone: 302-652-5070 / Fax: 302-652-0607

Juanita R. Brooks (brooks@fr.com)
Jonathan E. Singer (singer@fr.com)
W. Chad Shear (shear@fr.com)
Geoffrey D. Biegler (biegler@fr.com)
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Phone: 858-678-5070 / Fax: 858-678-5099

John M. Farrell (farrell@fr.com
FISH & RICHARDSON P.C.
500 Arguello Street, Suite 500
Redwood City, CA 94063

Boston, MA 02109
(617) 526-6000
Vinita.Ferrera@wilmerhale.com
Emily.Whelan@wilmerhale.com
Shirley.Cantin@wilmerhale.com

Attorneys for Plaintiffs Gilead Sciences, Inc. and Gilead Pharmasset LLC

Phone: 650-839-5070 / Fax: 650-839-0607

Attorneys for Plaintiffs Gilead Sciences, Inc. and Gilead Pharmasset LLC

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: March 14, 2018

Respectfully Submitted,

s/Keith J. Miller
Keith J. Miller (kmiller@rwmlegal.com)
ROBINSON MILLER LLC
One Newark Center, 19th Floor
Newark, New Jersey 07102
(973) 690-5400 (Telephone)
(973) 466-2760 (Facsimile)

Attorneys for Plaintiffs Gilead Sciences, Inc. and Gilead Pharmasset LLC